Case: 1:17-md-02804-DAP Doc #: 1919-12 Filed: 07/19/19 1 of 21. PageID #: 92396

## EXHIBIT 10

```
1
              UNITED STATES DISTRICT COURT
            FOR THE NORTHERN DISTRICT OF OHIO
2
                    EASTERN DIVISION
                                     MDL No. 2804
3
    IN RE: NATIONAL
    PRESCRIPTION OPIATE
                                     Case No.
    LITIGATION
                                     1:17-MD-2804
5
    THIS DOCUMENT RELATES TO
                                     Hon. Dan A.
                                     Polster
    ALL CASES
7
8
9
                  Tuesday, May 14, 2019
10
11
       HIGHLY CONFIDENTIAL - SUBJECT TO FURTHER
12
                 CONFIDENTIALITY REVIEW
13
14
15
            Videotaped Deposition of JAMES E.
16
     RAFALSKI, VOLUME 2, held at Weitz &
     Luxenburg PC, 3011 West Grand Avenue, Suite
17
     2150, Detroit, Michigan, commencing at
     8:25 a.m., on the above date, before
18
     Michael E. Miller, Fellow of the Academy of
     Professional Reporters, Registered Diplomate
19
     Reporter, Certified Realtime Reporter and
     Notary Public.
20
21
22
23
                GOLKOW LITIGATION SERVICES
24
             877.370.3377 ph | fax 917.591.5672
                     deps@golkow.com
25
```

1	APPEARANCES:
2	MCHUGH FULLER LAW GROUP
	BY: MICHAEL J. FULLER, ESQUIRE
3	mike@mchughfuller.com
	ALLAN "AJ" ELKINS, JR., ESQUIRE
4	aj@mchughfuller.com
	AMY QUEZON, ESQUIRE
5	amy@mchughfuller.com
	97 Elias Whiddon Road
6	Hattiesburg, Mississippi 39402
	(601) 261-2220
7	Counsel for MDL Plaintiffs
8	
9	KELLER ROHRBACK LLP
	BY: GARY A. GOTTO, ESQUIRE
10	ggotto@kellerrohrback.com
	3101 North Central Avenue
11	Suite 1400
	Phoenix, Arizona 85012
12	(602) 248-0088
1.2	Counsel for MDL Plaintiffs
13	DDANGMEMMED GMDANGII C TENNITNGG DIIG
T4	BRANSTETTER STRANCH & JENNINGS PLLC
15	BY: TRICIA HERZFELD, ESQUIRE triciah@bsjfirm.com@bsjfirm.com
12	223 Rosa L. Parks Boulevard
16	Suite 200
1.0	Nashville, Tennessee 37203
17	(615) 254-8801
/	Counsel for Tennessee Plaintiffs
18	
19	REED SMITH LLP
	BY: ABIGAIL M. PIERCE, ESQUIRE
20	abigail.pierce@reedsmith.com
- Annual Control of Co	1717 Arch Street
21	Suite 3100
	Philadelphia, Pennsylvania 19103
22	(215) 851-8100
	Counsel for AmerisourceBergen Drug
23	Corporation
24	<u>.</u>
25	

1	APPEARANCES:
2	WILLIAMS & CONNOLLY LLP
	BY: STEVEN M. PYSER, ESQUIRE
3	spyser@wc.com
	BRAD MASTERS, ESQUIRE
4	bmasters@wc.com
	725 Twelfth Street, N.W.
5	Washington, D.C. 20005
	(202) 434-5000
6	Counsel for Cardinal Health Inc.
7	
8	JONES DAY
:	BY: NEAL J. STEPHENS, ESQUIRE
9	nstephens@jonesday.com
	1755 Embarcadero Road
10	Palo Alto, California 94303
	(650) 739-3939
11	Counsel for Walmart Corporation
12	
13	ROPES & GRAY LLP
	BY: ANDREW O'CONNOR, ESQUIRE
14	andrew.o'connor@ropesgray.com
The state of the s	WILLIAM DAVISON, ESQUIRE
15	william.davison@ropesgray.com
	Prudential Tower
16	800 Boylston Street
	Boston, Massachusetts 02199
17	(617) 951-7000
1.0	Counsel for Mallinckrodt Pharmaceuticals
18	CONTROLL OF DISTANCE TO
19	COVINGTON & BURLING LLP
	BY: CHRISTOPHER K. EPPICH, ESQUIRE
20	ceppich@cov.com
01	1999 Avenue of the Stars
21	Los Angeles, California 90067
22	(424) 332-4800
22	Counsel for McKesson Corporation
23	
24 25	
45	

```
APPEARANCES:
 2
         COVINGTON & BURLING LLP
              MEGHAN MONAGHAN, ESQUIRE
3
               mmonaghan@cov.com
         One City Center
          850 Tenth Street, N.W.
         Washington, D.C. 20001
          (202) 662-6000
5
         Counsel for McKesson Corporation
6
         LOCKE LORD LLP
         BY: C. SCOTT JONES, ESQUIRE
               sjones@lockelord.com
8
         2200 Ross Avenue
         Suite 2800
9
         Dallas, Texas 75201
10
          (214) 740-8000
         Counsel for Henry Schein, Inc. and
11
         Henry Schein Medical Systems, Inc.
12
13
         FOLEY & LARDNER LLP
         BY: JAMES W. MATTHEWS, ESQUIRE
               jmatthews@foley.com
14
         111 Huntington Avenue
         Boston, Massachusetts 02199
15
          (617) 342-4000
         Counsel for Anda Inc.
16
17
18
         ARNOLD & PORTER KAYE SCHOLER LLP
              DAVID D. FAUVRE, ESQUIRE
         BY:
               david.fauvre@arnoldporter.com
19
         601 Massachusetts Avenue, N.W.
         Washington, D.C. 20001
20
          (202) 942-5000
         Counsel for Endo Health
21
         Solutions Inc., Endo
         Pharmaceuticals Inc., Par
22
         Pharmaceutical, Inc. and Par
         Pharmaceutical Companies, Inc.
23
24
25
```

ſ			
	1	A E	PPEARANCES:
	2		KIRKLAND & ELLIS LLP
			BY: ERICA B. ZOLNER, ESQUIRE
	3		erica.zolner@kirkland.com
			KAITLYN L. COVERSTONE, ESQUIRE
	4		kaitlyn.coverstone@kirkland.com
			300 North LaSalle
	5		Chicago, Illinois 60654
			(312) 862-2000
	6		Counsel for Allergan Finance LLC
	7		
	8		MORGAN LEWIS & BOCKIUS LLP
			BY: MAUREEN K. BARBER, ESQUIRE
	9		maureen.barber@morganlewis.com
			One Oxford Centre
	10		Thirty-Second Floor
			Pittsburgh, Pennsylvania 15219
	11		(412) 560-3300 Counsel for Teva Pharmaceuticals
	12		USA Inc., Cephalon Inc., Watson
	44		Laboratories Inc., Actavis LLC, and
	13		Actavis Pharma Inc. f/k/a Watson
			Pharma Inc.
	14		FIRETING FIFE.
-	15 .		ZUCKERMAN SPAEDER LLP
-			BY: GRAEME W. BUSH, ESQUIRE
	16		gbush@zuckerman.com
			PAUL B. HYNES, JR., ESQUIRE
	17		phynes@zuckerman.com
			(via teleconference)
	18		1800 M Street, N.W.
			Suite 1000
	19		Washington, D.C. 20036
			(202) 778-1800
	20		Counsel for CVS Indiana LLC and
	0.1		CVS Rx Services Inc.
	21 22		
	23		
	24		
	25		

```
APPEARANCES:
 2
          DECHERT LLP
               ERIK W. SNAPP, ESQUIRE
               erik.snapp@dechert.com
 3
          35 West Wacker Drive
          Suite 3400
 4
          Chicago, Illinois 60601
          (312) 646-5800
5
          Counsel for Purdue Pharma
6
          O'MELVENY & MYERS LLP
 7
          BY:
               AMY R. LUCAS, ESQUIRE
8
               alucas@omm.com
          1999 Avenue of the Stars
9
          8th Floor
          Los Angeles, California 90067
10
          (213) 430-6000
          Counsel for Janssen Pharmaceuticals Inc.
11
12
         MARCUS & SHAPIRA LLP
               JOSHUA A. KORBIN, ESQUIRE
          BY:
               korbin@marcus-shapira.com
1.3
          One Oxford Centre
          35th Floor
14
         Pittsburgh, Pennsylvania 15219
          (412) 471-3490
15
          Counsel for HBC Services
16
         BARTLIT BECK HERMAN PALENCHAR &
17
          SCOTT LLP
               KATHERINE M. SWIFT, ESQUIRE
18
         BY:
               katherine.swift@bartlit-beck.com
          54 West Hubbard Street
19
         Suite 300
20
         Chicago, Illinois 60654
          (312) 494-4400
21
         Counsel for Walgreens Company
22
23
24
25
```

```
APPEARANCES:
 2
         BARNES & THORNBURG LLP
               WILLIAM LEEDER, ESQUIRE
         BY:
3
               bill.leeder@btlaw.com
          171 Monroe Avenue, N.W.
         Suite 1000
         Grand Rapids, Michigan 49503
          (616) 742-3930
5
         Counsel for H.D. Smith
 6
7
         CAVITCH FAMILO & DURKIN CO. L.P.A.
         BY: ERIC J. WEISS, ESQUIRE
               eweiss@cavitch.com
8
               (via teleconference)
         1300 East 9th Street
9
         Cleveland, Ohio 44114
10
          (216) 621-7860
         Counsel for Discount Drug Mart
11
12
         FOX ROTHSCHILD LLP
         BY: STEPHAN A. CORNELL, ESQUIRE
               scornell@foxrothschild.com
13
               (via teleconference)
14
         2700 Kelly Road
         Suite 300
         Warrington, Pennsylvania 18976
15
          (215) 345-7500
         Counsel for Prescription Supply Inc.
16
17
         MORGAN LEWIS & BOCKIUS LLP
18
              CAROLYN A. SILANE, ESQUIRE
         BY:
               carolyn.silane@morganlewis.com
19
               (via teleconference)
20
         101 Park Avenue
         New York, New York 10178
21
         (212) 309-6000
         Counsel for Rite Aid
22
23
     VIDEOGRAPHER:
24
           David Lane,
           Golkow Litigation Services
25
```

## Case: 1:17-md-02804-DAP Doc #: 1919-12 Filed: 07/19/19 9 of 21. PageID #: 92404 Highly Confidential - Subject to Further Confidentiality Review

1	INDEX	
2		
3	APPEARANCES	412
	PROCEEDINGS	421
4		
5		:
6	EXAMINATION OF JAMES E. RAFALSKI:	
7	BY MS. SWIFT	421
8	BY MR. BUSH	562
	BY MR. O'CONNOR	630
9	BY MS. LUCAS	703
10	BY MS. ZOLNER	740
11	BY MR. SNAPP	776
12	BY MR. FAUVRE	794
13	BY MS. BARBER	810
14	BY MR. FULLER	829
15	BY MR. MATTHEWS	838
16		
17		
18	CERTIFICATE	842
	ERRATA	845
19	ACKNOWLEDGMENT OF DEPONENT	846
20	LAWYER'S NOTES	847
21		datatistemen
22		
23		
24		
25		- And the second

1	PROCEEDINGS
2	(May 14, 2019 at 8:25 a.m.)
3	THE VIDEOGRAPHER: We're now on
4	the record. My name is David Lane,
5	videographer for Golkow Litigation
6	Services. Today's date is May 14th,
7	2019. Our time is 8:25 a.m.
8	This deposition is taking place
9	in Detroit, Michigan in the matter of
10	National Prescription Opiate
11	Litigation. Our deponent today is
12	James E. Rafalski. Counsel will be
13	noted on the stenographic record.
14	Our court reporter today is
15	Mike Miller.
16	Mr. Rafalski, I just want to
17	remind you, you're still under oath
18	from yesterday.
19	THE WITNESS: Yes, sir, I
20	understand. Thank you.
21	EXAMINATION
22	BY MS. SWIFT:
23	Q. Good morning, Mr. Rafalski.
24	A. Good morning.
25	Q. We met a moment ago. My name

```
what they distribute, but that doesn't mean
 1
 2
      exclusively, just...
 3
            0.
                   Fair enough.
 4
                    So in that situation that you
 5
     described was the predominant situation, when
     a manufacturer is selling to a distributor,
 6
 7
     the distributor places an order with the
 8
     manufacturer in those circumstances, right?
 9
            Α.
                   Yes, sir.
10
                    Okay. And the manufacturer
            Ο.
11
     ships product to the distributor?
12
            Α.
                   That's correct.
13
            Ο.
                   Now, in your report you
     describe five suspicious order methodologies,
14
15
     correct?
16
            Α.
                   I do.
17
                   But your report does not apply
            Ο.
     any of those five methodologies to orders
18
     submitted by distributors to manufacturers,
19
20
     correct?
21
            Α.
                   That's correct.
22
                   And so your report doesn't
            Ο.
     identify any orders received by a
23
24
     manufacturer that were suspicious, correct?
25
                    I don't think that it says
            Α.
```

- that. It's just that I wasn't tasked to
- 2 provide that methodology in regards to
- 3 manufacturers at this time.
- Q. I understand. But your report
- 5 doesn't identify any suspicious orders that
- 6 were submitted by distributors to
- 7 manufacturers.
- A. My report would only identify
- those orders that the manufacturers have
- identified. I don't make any independent
- calculations or apply any algorithms to
- identify it outside of what's in my report
- stated as I've discovered as part of this
- discovery.
- Q. Okay. So other than the
- reports that the manufacturers themselves
- reported to DEA, you have not identified any
- suspicious orders submitted by distributors
- 19 to manufacturers, correct?
- 20 A. Can I ask a clarification? Are
- you talking about an individual order or are
- you talking about conduct?
- Q. I'm talking about individual
- orders.
- A. I have not done that as we sit

- here today, no, sir.
- Q. Okay. So your report does not
- identify any shipments by manufacturers to
- 4 distributors that you claim should have been
- 5 reported as suspicious?
- A. My opinion goes to whether or
- 7 not there were effective -- or suspicious
- 8 orders, effective suspicious order systems in
- 9 place and/or the maintenance of effective
- controls, the due diligence. I do not do any
- calculations that would identify any specific
- orders.
- Q. Okay. So just to be clear, in
- response to my question, your report does not
- identify any shipments by manufacturers to
- distributors that you claim should have been
- reported as suspicious, correct?
- 18 A. I think there's some instances
- in my report, there was -- there may be a
- description of a relationship or some
- 21 transactions between a -- let me think a
- second.
- Q. Uh-huh.
- A. Because I have all of the
- different companies.

```
1
                    (Document review.)
 2
                    I don't believe so, no, sir.
            Α.
      BY MR. O'CONNOR:
 3
                          And at trial, do you
 4
            Ο.
                   Okay.
      intend to offer any opinion regarding whether
 5
 6
      any particular order submitted to a
 7
      manufacturer was suspicious?
            Α.
                   If I'm requested to do that
 9
      analysis by counsel, I quess that would be a
10
      possibility. I haven't done the analysis as
11
      today, so I couldn't offer that opinion.
12
                   So as you sit here today, you
13
      do not have an opinion on whether any
14
      particular order that was shipped by a
     manufacturer was suspicious?
15
16
            Α.
                   I think I have an opinion.
17
                   But you haven't identified any
            Ο.
18
      order, correct?
19
                   I have not identified a
            Α.
20
      specific order, but I have an opinion on the
21
      conduct.
                   And are you offering any
22
            Ο.
23
     opinion in this litigation that any
24
     particular order that was shipped into Summit
25
     or Cuyahoga Counties was suspicious?
```

- Q. What are we doing here? Are
- you saying that you're doing something
- here -- you reviewed SOPs for this report,
- 4 correct?
- 5 A. Yeah, but not in the capacity
- 6 as a diversion investigator.
- 7 Q. Are you saying that you're
- 8 doing something in this report that you would
- 9 not have done as a diversion investigator?
- MR. FULLER: Object to form.
- That wasn't the question you asked.
- 12 A. No, I think you're asking me to
- comment on my actions that I would conduct at
- a registrant's location as a diversion
- investigator, and I'm not sure that that
- 16 conduct would be readily available, unless I
- misunderstood your question.
- 18 BY MS. LUCAS:
- 19 Q. I'm not -- I just want a yes or
- no, whether it's common for DEA investigators
- 21 to ask for SOPs during a regulatory
- 22 investigation.
- A. I don't -- I don't know.
- Q. In your experience.
- A. I don't know what's common for

all diversion investigators, so I don't know. 2 Fair. In your experience? Q. 3 Α. Yes. 4 Now, during these regulatory Q. 5 investigations, if the DEA in your experience 6 had concerns about a manufacturer's suspicious order monitoring program that they 8 observed during the inspection, the DEA would 9 raise those concerns with the registrant, 10 right? 11 MR. FULLER: Object to form. 12 Again, it goes to DEA's policy 13 on investigations and their position 14 and what they raise and what they 15 don't raise, so I would say that's 16 outside of your Touhy authorization, 17 Mr. Rafalski. 18 THE WITNESS: I'd agree with 19 I'm not going to answer based 20 on the Touhy letter. 21 BY MS. LUCAS: 22 You can't tell me whether in 23 your experience if there were concerns about 24 a suspicious order monitoring program that 25 you observed during a regulatory

- 1 A. Yes, or the nonabuse rates.
- Q. The geographic location or
- 3 where they're being sold?
- 4 A. Yes.
- 5 O. The sales volume in that
- 6 qeography?
- 7 A. That could be another factor,
- 8 yes, ma'am.
- 9 Q. All right. I'm going to ask
- you some quick yes or nos and then I need to
- 11 pass the witness while reserving my rights
- since I have many, many more questions for
- 13 you.
- Do you know how many customers
- Janssen had during the time it sold
- 16 Duragesic?
- A. No, I do not.
- 18 Q. Do you know how many customers
- Janssen had during the time it sold Nucynta?
- 20 A. I have not evaluated that
- information as far as the ARCOS, so, no, I do
- 22 not at this time.
- Q. Do you know how many orders per
- 24 month Janssen received from its customers for
- 25 Duragesic?

No, I do not at this time. 1 Α. 2 Q. Do you know how many orders per month Janssen received from its customers for 3 4 Nucynta? No, I do not, not at this time. 5 Α. 6 Ο. Do you know Janssen's market share for its opioid medications sold in the 7 Track 1 jurisdictions? No, I do not at this time. 9 10 Do you know the rates of Ο. diversion for Duragesic or Nucynta in the 11 Track 1 jurisdictions? 12 I'm not sure there's any 13 Α. 14 analysis or information available to give any concise rate of diversion of any drug. 15 16 So is that a no? Ο. I think that's a no. 17 Α. Do you know how many shipments 18 Ο. of Duragesic Janssen flagged through its 19 20 algorithm and investigated as potentially 21 suspicious? 22 Α. Janssen's never reported a suspicious order to the DEA. 23 My question was different. 24 Ο. 25 Oh, I'm sorry. Misunderstood Α.

1	it then.
2	Q. Do you know how many shipments
3	of Duragesic Janssen's algorithm flagged and
4	Janssen subsequently investigated before
5	releasing?
6	A. I do not.
7	Q. Do you know how many shipments
8	of Nucynta Janssen flagged as potentially
9	suspicious and investigated before releasing?
10	A. I didn't do that type of
11	analysis up to today on that, on the data in
12	regards to those products and that
13	registrant.
14	Q. Yes or no, did you know that
15	Janssen has reported a physician to the DEA
16	based on a sales representative's tip?
17	A. I have not reviewed a document
18	that had indicated that to me, no, ma'am.
19	Q. Do you know of any instance in
20	the Track 1 jurisdictions of Duragesic being
21	diverted?
22	A. At this time, no, ma'am.
23	Q. Do you know of any instance in
24	the Track 1 jurisdictions of Nucynta being
25	diverted?

	1	A. At this time, no, ma'am.
L	2	Q. Do you know how many
	3	inspection or strike that.
	4	Do you know how many regulatory
	5	investigations Janssen strike that again.
	6	Do you know how many DEA
	7	regulatory investigations of Janssen
	8	distribution centers were conducted during
	9	the relevant time period in this case?
	10	A. I do not because that
	11	information would not be available to me.
<del></del>	12	Q. Are you aware, yes or no, that
	13	the DEA conducted multiple regulatory
	14	investigations of Janssen using at least 14
	15	different DEA diversion investigators since
***************************************	16	2008?
	17	A. Were those regulatory
	18	investigations that I'm sorry, with your
	19	question
	20	Q. Were you aware of
	21	A. Could you answer
	22	Q. Well, let me
	23	A. Could you restate that for me?
	24	Just whether it was inspections or regulatory
A William Town	25	investigations, I just need clarification.

1 CERTIFICATE 2 I, MICHAEL E. MILLER, Fellow of the Academy of Professional Reporters, Registered Diplomate Reporter, Certified 3 Realtime Reporter, Certified Court Reporter and Notary Public, do hereby certify that 4 prior to the commencement of the examination, JAMES E. RAFALSKI was duly sworn by me to 5 testify to the truth, the whole truth and nothing but the truth. 6 I DO FURTHER CERTIFY that the foregoing is a verbatim transcript of the testimony as taken stenographically by and 8 before me at the time, place and on the date hereinbefore set forth, to the best of my ability. 10 I DO FURTHER CERTIFY that pursuant to FRCP Rule 30, signature of the witness was 11 not requested by the witness or other party before the conclusion of the deposition. 12 I DO FURTHER CERTIFY that I am 13 neither a relative nor employee nor attorney nor counsel of any of the parties to this 14 action, and that I am neither a relative nor employee of such attorney or counsel, and 15 that I am not financially interested in the 16 action. 17 18 MICHAEL E. MILLER, FAPR, RDR, CRR Fellow of the Academy of Professional Reporters 19 NCRA Registered Diplomate Reporter NCRA Certified Realtime Reporter 20 Certified Court Reporter 21 Notary Public My Commission Expires: 7/9/2020 22 Dated: May 15, 2019 23 24 25